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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,554	04/07/2005	Hiroyuki Sato	10936-86	8861
•	10/530,554 04/07/2005 Hiroyuki Sato 10936-86 8861 24256 7590 11/26/2007 DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202 1796	INER		
1900 CHEMED	CENTER	MESH, GENNADIY		
			ART UNIT	PAPER NUMBER
,			1796	
			MAIL DATE	DELIVERY MODE
	•		11/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Applicant(s)			
		10/530,554	SATO ET AL.			
		Examiner	Art Unit			
		Gennadiy Mesh	1796			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DYNAMINS OF A CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Of period for reply is specified above, the maximum statutory period ware to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. sely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status			•			
1)🖂	Responsive to communication(s) filed on 23 O	<u>ctober 2007</u> .				
2a) <u></u> ☐	This action is FINAL . 2b)⊠ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposit	ion of Claims					
5)□ 6)⊠ 7)□	Claim(s) 1,4 and 6-22 is/are pending in the app 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) 1,4 and 6-22 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.				
Applicati	ion Papers					
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
, 11)	The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority ι	under 35 U.S.C. § 119					
a)(Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priorical application from the International Bureau See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive (PCT Rule 17.2(a)).	on No ed in this National Stage			
			•			
Attachmen	t(s)					
1)	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te			

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2007 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1,4, 6 and 10 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and in further view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94(hereafter HTP).

Regarding Claim 1 and 4 Shinoda discloses preparation (see abstract) process of polyester with desirable MW(molecular weight) or melt viscosity(note, that melt viscosity of a **resulting aliphatic polyester** polymer is proportional function of the MW of the polyester) from cyclic esters or their mixtures (see lines 5 –15,column 1), wherein impurities as water and hydroxycarboxylic acids (including oligomers) are accurately controlled (thus proton concentration also controlled) with total amount less

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than 100 ppm (see abstract, lines 40 - 68, column 2, line 5-7, column 3 and line 50, column 6) in order to produce polyester with desirable MW (see lines 1-5, column 3).

Shinoda is silent about addition of water to polymerization system. However, addition of water in order to start ring-opening polymerization process is known in the art. For example, Howelton teach addition of water (as polymerization initiator) in ring opening polymerization(see line 20, column 1).

Therefore, it would have been obvious to one of ordinary of skill in the art to use purified cyclic ester in order to obtain polyester with desirable MW (or melt viscosity) per teaching of Shinoda and add water to polymerization system in order to start or/and increase rate of polymerization as it shown by Howelton.

Shinoda in view of Howelton silent about conducting polymerization in closed volume – particularly inside closed tubes as it claimed by Applicant in Claim 1 and 11.

However, ring -opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process - no volatile byproducts are generated during polymerization process as it disclosed in HTP (pages 90-94).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton inside closed tubes (as a simple polymerization reactors), as it claimed by Applicant, due to significant reduction of overall cost of production equipment due to simplicity of this type or reactors (tube).

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Regarding Claim 12 Shinoda in view of Howelton silent about conducting polymerization in solid state after initial polymer was produced.

However, solid-state polymerization of polyesters in order to increase MW (or melt viscosity) of the polymer is well known in the art and would be obvious extension of polymerization process as it disclosed in HTP(pages 80 –82).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton with following step of solid-state polymerization as it thought in HTP in order to increase MW of the final polymer.

Subject mater claimed by Applicant in Claims 13 – 16 was discussed above.

Also see Shinoda: lines 5-17, column 1; lines 20 – 25, column 6 and Example 6, wherein copolymer of glycolide and other cyclic monomer is disclosed.

Regarding Claims 17 – 20: Shinoda in view of Howelton discloses substantially same process capable of producing substantially same product as a polyester with same MW. It will be reasonable to believe that other properties as viscosity and Yellowness index will be also substantially same. Burden shits to Applicant provide factual results to the contrary.

2. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and HTP(hereafter HTP), as applied to claims 1,4,6 and 13 –20 above, and further in view of Early (US 6,437,565).

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Regarding Claims 7 – 9: as it shown by Shinoda in view of Howelton and HTP impurities and proton concentration –(see above) are controlled factor in preparation process of the polyester with desirable MW (or melt viscosity as it explained above – see paragraph 1), but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer.

However, regressional analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

Response to Arguments

- 3. Applicant's arguments filed October 23,2007 have been fully considered but they are not persuasive.
- 3.1. Regarding Applicant's arguments related to Claims 1,3-6 and 13 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918):

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i) As it was stated in original rejection- Shinoda disclosed process wherein polymer with desirable characteristics is obtained by controlling impurities that contribute to overall proton concentration:

"The cyclic ester compound used in the invention is preferably dehydrated as much as possible before subjecting to the polymerization reaction. When the moisture content is high, molecular weight control of polyester is liable to be difficult. Consequently, moisture content of the cyclic ester compound is preferably 0.5% by weight or less, more preferably 1,000 ppm by weight or less. In order to accurately control the molecular weight of polyester having a molecular weight of 100,000 or more in particular, moisture content of the cyclic ester compound is preferably 100 ppm by weight or less." (Column 6, lines 39-50) — thus, first Applicant's argument is not persuasive.

- ii) Shinoda as a Primary reference does not need teach all elements of Applicant's Claims 1,3-6and 13-20. Adding water to the polymerization system was taught by Secondary reference as Howelton. Thus, Applicants second argument is not persuasive.
- iii) Regarding amount of volatile matter in the melt: it is clear that all additional compounds, including moisture (water or /and monomer) can act as a plasticizer and affect melt viscosity of the **melt**, comprising melted polyester. However, melt viscosity of the **pure polyester** is a function of MW of the polyester. As it was point out above,

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language of Claim 1 directed to "resulting aliphatic polyester" – arguments directed to amount of volatile matter is irrelevant to claimed subject matter of Claims 1 and 3 – 20.

- regulator note, that language of Applicant's claims is open to any additional compounds and is not specifically exclude lauryl alcohol from claimed subject matter.
- 3.2. Regarding Applicant's arguments related to Claims 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) as applied to claims 1-6 and 13 –20 above, and further in view of Early (US 6,437,565).

As it was discussed in original rejection, Shinoda in view of Howelton teach that impurities and proton concentration (see above) are controlled factor in preparation process of the polyester with desirable MW, but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer. Note, that regressional analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

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3.3. Regarding Applicant's Arguments related to Claims 10-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) as applied to claims 1-6 and 13 –20 above, and further in view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94 (hereafter – HTP):

- i). Regarding Applicant's arguments (see page 17 of Remarks) conducting ring-opening polymerization in closed volume HTP teach that ring-opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process no volatile byproducts are generated during polymerization process it is obvious, **based on this teaching**, to conduct polymerization in closed volume.
- ii) Note, when ring-opening polymerization is completed- all cyclic structures are opened than low molecular weight polymers can be subjected to SSP (Solid state polymerization) as it routinely done in the art.

Conclusion

THIS ACTION IS NOT MADE FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gennadiy Mesh whose telephone number is (571) 272 2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Gennadiy Mesh Examiner Art Unit 1796

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